**Policy: Post Transplant: Hepatitis B Prophylaxis in Liver Transplant Recipients Given Grafts from HBV POSTIVE DONORS**

**Statement: Policy Statement**: The Emory Transplant Center will comply with all applicable federal, state, and local laws, regulations, and policies regarding the management of prescribing medications and refills.

**Basis**: This policy is necessary for the protection of patients, physicians, and staff.

**Administrative Responsibility**: Section heads, physicians, practitioners, and staff are responsible for compliance with this policy:

**Scope/Procedure:**

**Hepatitis B Prophylaxis Protocol in Liver Transplant Recipients of Hepatitis B Core Antibody (HBcAb)-Positive Donors (HBsAg-negative)**

**Background**: Use of HBcAb liver grafts has helped to expand to donor organ pool. Reactivation or recurrence of Hepatitis B virus following orthotopic liver transplantation (OLT) of hepatitis B core antibody (HBcAb) positive livers historically carried a 50-95% risk of transmitting HBV to the recipients; however the use of combination prophylaxis consisting of hepatitis B immune globulin (HBIG) and a nucles(t)ide analog has markedly decreased recurrence rates and improved graft and patient survival rates after transplantation. With the introduction of nucleoside with much improved resistance profiles, recent data suggest that strategies with less dependence on HBIG and the indefinite use of entecavir coupled with periodic lab surveillance and high-dose HBV vaccinations are effective.

Due to a significantly higher risk of transmitting HBV to the recipient, **transplantation of grafts from donors that are HBsAg-positive into HBsAg-negative recipients is contraindicated.** Grafts from patients that are HBsAg positive and HBcAb positive or negative may be transplanted into recipients that are HBsAg-positive (refer to the post transplant hepatitis B prophylaxis in HBV positive recipients protocol)

**Purpose**: To prevent hepatitis B virus recurrence/reactivation in HBcAb positive donor-grafts.

**Pre-Liver Transplant:** Check hepatitis B surface Antigen (HBsAg), hepatitis B surface antibody (HBsAb), and hepatitis B core antibody (HBcAb) immediately prior to transplant. Mid-level practitioner or physician must order or cosign when placing other pre-operative orders. Attempt at vaccination of all pre-transplant HBsAb negative patients should be considered.

**Post-Liver Transplant (donor HBcAb-positive, HBsAg-negative):**

**If recipient is HBsAg-negative and HBsAb-negative (irrespective of HBcAb status), patient is considered to be at relatively high-risk of reactivation.** No HBIG is necessary.Patient is to receive indefinite oral antiviral treatment with entecavir 0.5 mg daily (adjusted per renal function). Tenofovir 300mg daily (adjusted per renal function) can be another option. Attempt at vaccination should be done 1 year after transplant. The high-dose vaccine (40 mcg) should be administered at 0, 1, and 6 months. The HBsAb should be then checked over 1 month after last dose. If the patient has successful sero-conversion of HBsAb the oral anti-viral therapy can then be stopped. If the HBsAb is negative (unsuccessful vaccination) then oral antiviral therapy should be continued indefinitely.

**If recipient is HBsAg-negative and HBsAb-positive (irrespective of HBcAb status) then patient is considered low-risk**. **No HBIG or oral antiviral therapy is given.** However HBsAb should be rechecked every six months; if it becomes negative than revaccination should be attempted with high-dose vaccine (as above). If vaccination fails (HBsAb is negative) then indefinite antiviral therapy with entecavir 0.5 mg is given daily.

**If recipient is HBsAg-positive, follow the post-transplant hepatitis B prophylaxis in HBV positive recipients protocol for details on peri-operative HBIG and oral anti-viral therapy.** Transplantation of grafts from donors that are HBsAg-positive into HBsAg-negative recipients is contraindicated.

**Laboratory Monitoring** All labs must be reviewed with a hepatologist. All medications and laboratory orders must be cosigned by a physician or licensed mid-level provider.

**HBV DNA Ultraquant PCR** and **Hepatitis B Surface Antigen** (HBsAg) should both be drawn pre-operatively and then at the following intervals:

0-12 months post-transplant: every 3 months

After 1 year post-transplant: every 6 months indefinitely

Approved by Liver Leadership Group

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